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(54) Investigating substances in bloodstream and detecting blood flow

(57) When investigating substances in a patient's bloodstream by non-invasively measuring the partial pressure of gas in the bloodstream using a transcutaneous gas sensor, a warning indication is provided of any reduction in capillary blood flow rate (due to shock or other physiological conditions), under which reduced flow condition the sensor readings are unreliable, by means of a flow detector device (6) incorporated into the sensor. Impedance measurements are made for non-invasive assessment of capillary blood flow rates by causing an alternating electric current to flow along a conduction path 16 confined substantially to the depth (D) of the capillary bed (5). Current is applied by outer electrodes (14) and (15) and the voltage drop is measured either across these electrodes or between inner electrodes (18 and 19) of a flow detector (6).

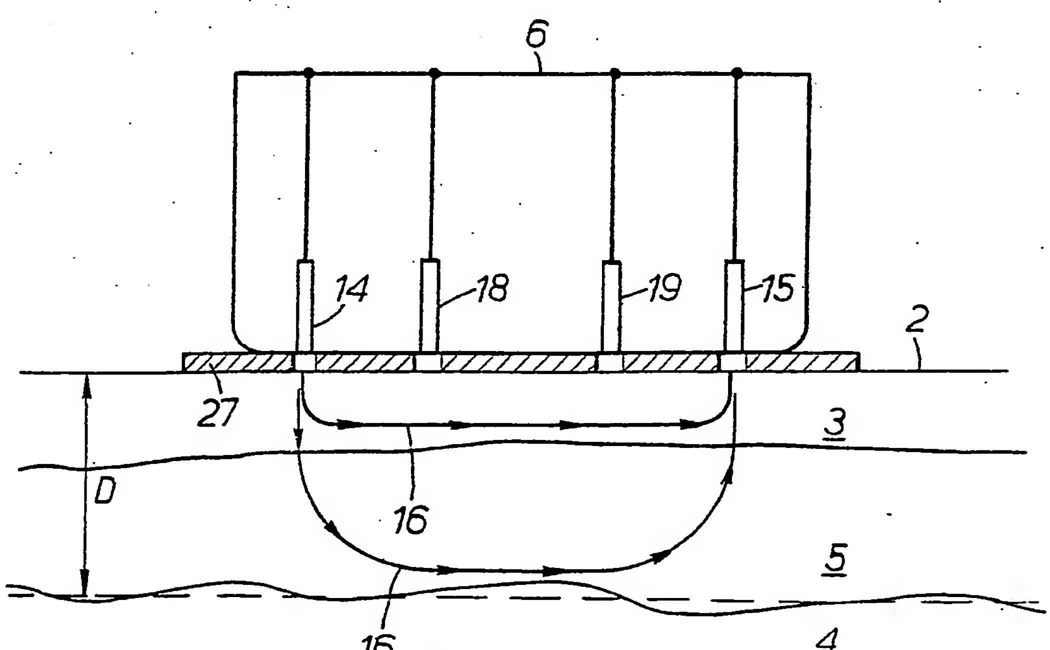

FIG. 1.

The drawings originally filed were informal and the print here reproduced is taken from a later filed formal copy.

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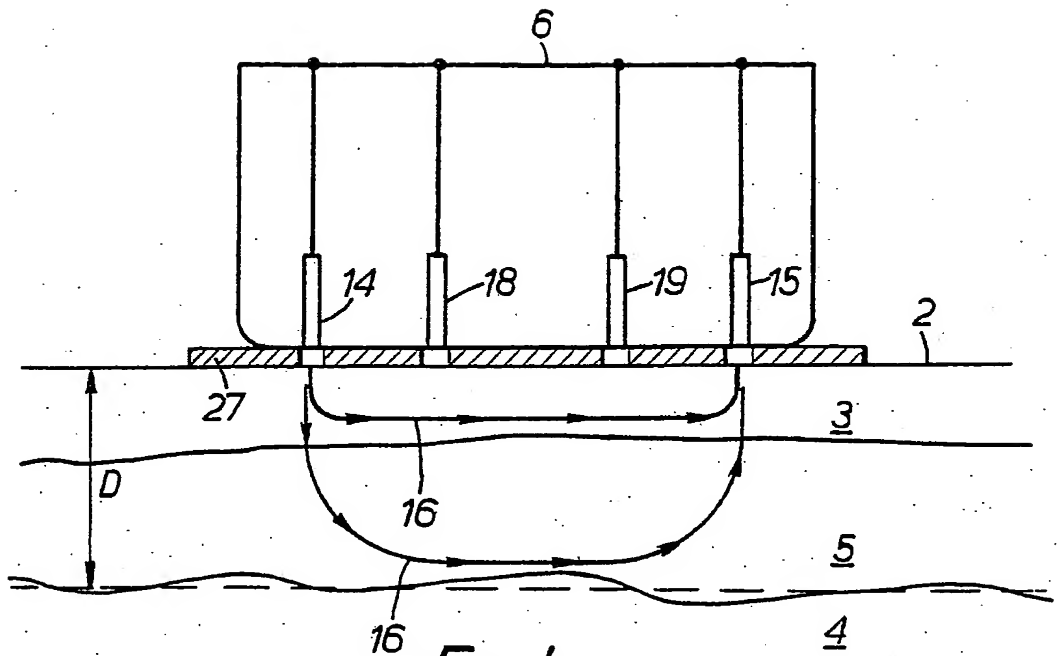

FIG. 1.

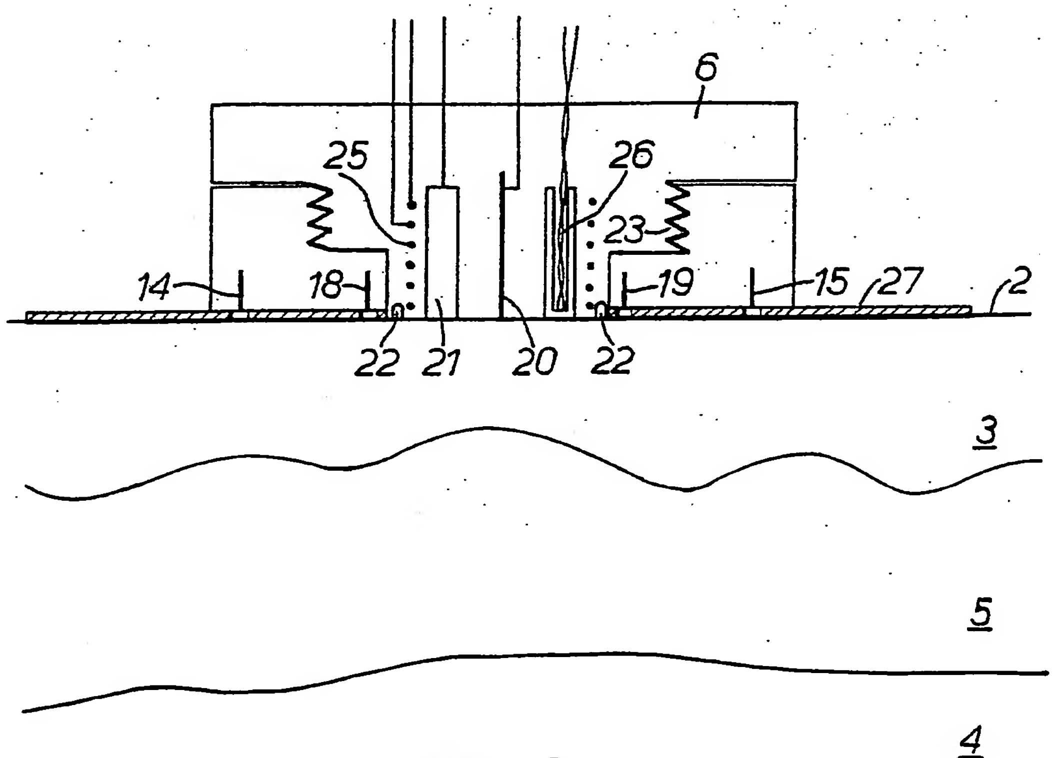

FIG. 2.

SPECIFICATION

Investigating substances in a patient's bloodstream

The present invention is concerned with the non-invasive investigation of substances in a patient's blood-stream. These substances will generally be capable of passing transcutaneously from the capillary blood vessels or loops to the skin surface. In particular the invention is concerned with capillary blood flow detectors and sensors incorporating such detectors. These are expected to find particular application in determining gas (such as oxygen or CO_2) partial pressure in blood and also blood flow rates, using in each case a non-invasive measuring technique. The invention could, however, be used for measuring glucose concentration for example. For the avoidance of doubt, "patient" is used throughout this specification to mean a human, animal or other creature, whether healthy or ill.

It is known to determine the partial pressure of a gas, e.g. oxygen, in the blood stream of a patient by inserting a catheter through the skin and into an artery to make the necessary measurement. However the use of a catheter can involve risk to the patient's life and in any event will cause discomfort to the patient. To overcome this difficulty, transcutaneous gas sensors have been devised which merely have to be held against a body surface of a patient without having to immerse any part of the sensor in blood. These gas sensors utilise the phenomenon that gas in the bloodstream, when carried close to the skin surface by the capillary loops or vessels branching out from the main arteries and contained within a layer (capillary bed) between the arterial region (containing the main arteries) and the skin surface layer (consisting of the epidermis and sub-epidermal region), diffuses through the skin surface layer to the outer surface where a transducer produces a signal related to the partial pressure of the gas in the capillary loops.

In general, it is the partial pressure of the *arterial* gas which needs to be determined and not that of the blood in the capillary loops. However, it has been found that by locally heating the skin surface using a transcutaneous gas sensor of the thermal stimulation type which includes its own controlled heater for maintaining the local skin temperature at a predetermined, elevated, temperature, the capillary loops open further to receive an increased blood flow such that the capillary loops now contain arterial blood. The resulting measurement made by the transcutaneous gas sensor is then closely equivalent to the partial pressure of the gas in the arterial bloodstream.

It is also known that skin blood flow can be reduced significantly by physiological processes (for example when the patient is under a state of shock) and so that measurement obtained from a skin mounted transcutaneous gas sensor of the thermal stimulation type may not always accurately indicate the arterial value. Additionally, if a reduction in capillary blood flow occurs without detection, damage to the skin surface may result since in removing the cooling effect on the heat produced by the oxygen sensor by the flow of blood through the capillary loops, the skin temperature immediately beneath the gas sensor will rise.

According to the invention from one aspect, there is provided a sensor device to be held against a body surface of a patient for use in investigating substances in the bloodstream, comprising a support body, a transcutaneous sensor of the thermal stimulation type on the support body for determining non-invasively a property of a substance in a patient's bloodstream, and a flow detector device for assessing non-invasively the blood flow rate in a region of the capillary bed positioned beneath the transcutaneous sensor, the flow detector device comprising means on the support body for applying alternating current, with the sensor device held against a body surface of the patient, between first and second spaced-apart points on the patient's body so that current will flow along a path within the patient's body extending between said points, the arrangement of the current applying means being such that the current carrying path is confined substantially to the depth of the capillary bed, and means on the support body for enabling the voltage drop along at least part of the length of the current path within the patient's body to be measured to provide an indication of the capillary blood flow rate.

The function of the flow detector device is that if the measured capillary flow rate falls below an appropriately selected predetermined value, the indicated property of the substance under investigation in the bloodstream (e.g. gas partial pressure value provided by the gas sensor) would be discarded as unreliable.

The output reading of the flow detector device could be observed by an operator but, preferably, the sensor device further comprises means arranged to provide an indication if the blood flow rate assessed by the flow detector device falls below a predetermined level. Alternatively or in addition, means can be provided arranged to prevent the effective use of the transcutaneous sensor if the blood flow rate assessed by the flow detector device falls below a predetermined level.

Alternatively, the sensor device may further comprise a visual display device arranged to provide respective displays on the same time base of said property, determined by the transcutaneous sensor, and of the blood flow rate assessed by the flow detector device. The particular method of displaying the measured information is of particular assistance when the apparatus is manned. Usually, the transcutaneous sensor will be a transcutaneous oxygen or CO_2 sensor for determining the partial pressure of oxygen or CO_2 in the bloodstream.

According to the invention from a second aspect, there is provided a flow detector device

for use in assessing non-invasively capillary blood flow rate in a patient, comprising a support body, means on the support body for applying alternating current, with the flow detector device held against a body surface of the patient, between first and second spaced-apart points on the patient's body so that current will flow along a path within the patient's body extending between said points, the arrangement of the current applying means being such that the current carrying path is confined substantially to the depth of the capillary bed, and means on the support body for enabling the voltage drop along at least part of the length of the current path within the patient's body to be measured to provide an indication of the capillary blood flow rate.

The current applying means and the voltage drop measuring means can together be constituted by first and second spaced-apart electrodes across which alternating current may be applied and the voltage drop measured. In a preferred arrangement, however, the current applying means comprises first and second spaced-apart electrodes and the voltage drop measuring means comprises third and fourth electrodes which are both arranged between the first and second electrodes and have a mutual separation.

In accordance with a further method of assessing non-invasively capillary blood flow rate in a patient, alternating current is applied between two spaced-apart points on a body surface of the patient so as to cause current to flow along a path within the patient's body extending between said points and confined substantially to the depth of the capillary bed, and the voltage drop along at least a part of the length of said path is measured to provide an indication of the capillary blood flow rate.

For a better understanding of the invention and to show how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:

Figure 1 shows an "impedance type" flow measuring device, and

Figure 2 shows a sensor device including a transcutaneous gas sensor and a flow detector device similar to that shown in Figure 1.

Referring to Figure 1, a flow detector device 1 is shown held in position against a body surface 2 of a patient by double-sided sticky tape 27. Reference 3 represents the skin surface layer, reference 4 represents the arterial region of the patient's body where the main arteries of the patient's bloodstream are situated, and capillary loops or vessels which lead blood from the main arteries close to the skin surface and then return the blood back to the main venous blood stream are contained within the capillary bed 5 which is a layer disposed between the skin surface layer 3 and arterial region 4. The sticky tape 27 is applied between the undersurface of a support body 6 and the patient's body surface 2. Embedded in the support body, which consists of electrically insulative material, are two electrodes 14, 15 with respective connection leads shown very diagrammatically in Figure 1. Holes are provided in the sticky tape in register with the electrodes 14, 15 and these holes are filled with an electrically conductive gel. In this way, the electrodes are maintained in electrically conductive connection with the body surface 2, so that alternating current of constant amplitude applied to these electrodes will cause a current to flow between the electrodes along a current carrying path within the patient's body. The boundaries of the current flow path (shown very schematically—at 16—but being in practice less well-defined than actually indicated) are confined substantially to the skin surface layer 3 and capillary bed 5 but do not extend into the arterial region 4. In other words, the current carrying path is confined substantially to the depth of the capillary bed. Two further electrodes 18, 19 arranged in the same manner in the support body 6 as the electrodes 14, 15 are positioned between the electrodes 14, 15 and are mutually separated from one another.

The current passing through the body between the electrodes 14, 15 causes a voltage drop to be established across the electrodes 18, 19. The amplitude of this voltage is related to the electrical impedance of the tissue beneath the flow detector device, and this is strongly influenced by the relative proportions of highly conductive blood and poorly conductive skin and tissue. Furthermore, it can be demonstrated that the impedances presented by the different electrode/gel/body surface connections can be taken to be largely self-cancelling, so far as having any effect on the voltage drop is concerned. Also, it can be assumed that the voltage drop produced by the current flowing through the skin surface layer 3 is independent of blood flow changes in the capillary loops. Thus the amplitude of the voltage provides a relatively reliable indication of the capillary blood flow rate.

In a simplified embodiment, only two electrodes are provided embedded in the support body. Alternating current of constant amplitude is applied between these electrodes and the voltage drop across the electrodes measured to give an indication of the capillary blood flow rate. However, although simpler this embodiment is less advantageous because the impedances existing at the different electrode/gel/body surface connections introduce inaccuracies.

It must be stressed that the described flow detector devices merely give an assessment of blood flow rate changes, i.e. they give qualitative rather than quantitative results. Nevertheless, such indications can, for certain purposes, be very useful, particularly in the application now to be described to certain transcutaneous measurements.

Referring now to Figure 2, there is shown a sensor device for investigating partial pressure of gas (usually oxgyen or CO_2) in blood which incorporates a transcutaneous oxygen or CO_2

sensor mounted on the support body 6, the sensor comprising an electrochemical oxygen cell comprising a cathode 20, anode 21, and a reservoir 22 containing electrolyte trapped behind a membrane 23, this membrane being trapped between two screw-together parts which make up the support body. The transcutaneous sensor 17 also includes an electrical heating coil 25 controlled by a thermistor 26 so as to raise and maintain the skin surface temperature immediately beneath the electrochemical cell at a predetermined temperature, typically 43°C. Under such conditions of thermal stimulation, the blood flow from the arteries into the capillary loops or vessels is increased and oxygen concentration in the capillary loops becomes very similar to that actually existing in the main arteries. Therefore, the output reading determined from the electrochemical cell represents the true arterial gas partial pressure.

Also mounted on the support body 6 is a flow detector device 1 of essentially identical construction to that shown in Figure 1, there being a large central hole cut in the sticky tape 27 to allow the membrane 23 to be positioned so as to be contacted by gas which has passed transcutaneously to the skin surface 2. The output of the flow detector can be processed to serve as a warning when the capillary flow rate falls below a predetermined level, which would be arbitrarily chosen such that the reading given by the electrochemical cell of gas partial pressure would differ from the reading under normal, thermally stimulated, flow conditions sufficiently that the reading would be regarded as one which should be discarded. The output could be used to provide a visual and/or audible warning such that an operator would then discard the output data from the electrochemcial cell as long as the warning is present. In one preferred arrangement, the outputs from the electrochemical cell and flow detecting device can be presented simultaneously on a visual display device with the two sets of data arranged on the same time base. For example, the display device could be a dual pen recorder. Then, the tracings on the recording sheet could be observed periodically and the parts of the gas partial pressure data which are to be discarded would be readily apparent at a glance from the detected capillary blood flow rate tracing. In another preferred arrangement, a suitable control circuit could be used automatically to render the electrochemical cell ineffective in the event of the flow detector device indicating that the flow capillary blood flow rate has fallen below the predetermined level indicative of normal flow under thermally stimulated conditions.

Claims

1. A flow detector device for use in assessing non-invasively capillary blood flow rate in a patient, comprising a support body, means on the support body for applying alternating current, with the flow detector device held against a body surface of the patient, between first and second spaced-apart points on the patient's body so that current will flow along a path within the patient's body extending between said points, the arrangement of the current applying means being such that the current carrying path is confined substantially to the depth of the capillary bed, and means on the support body for enabling the voltage drop along at least part of the length of the current path within the patient's body to be measured to provide an indication of the capillary blood flow rate.

2. A flow detector device according to claim 1, wherein the current applying means and the voltage drop measuring means are together constituted by first and second spaced-apart electrodes across which alternating current may be applied and the voltage drop measured.

3. A flow measuring device according to claim 1, wherein the current applying means comprises first and second spaced-apart electrodes and the voltage drop measuring means comprises third and fourth electrodes which are both arranged between the first and second electrodes and have a mutual separation.

4. A flow measuring device substantially as hereinbefore described with reference to Figure 1 of the accompanying drawings.

5. A sensor device to be held against a body surface of a patient for use in investigating substances in the bloodstream, comprising a support body, a transcutaneous sensor of the thermal stimulation type on the support body for determining non-invasively a property of a substance in a patient's bloodstream, and a flow detector device for assessing non-invasively the blood flow rate in a region of the capillary bed positioned beneath the transcutaneous sensor, the flow detector device comprising means on the support body for applying alternating current, with the sensor device held against a body surface of the patient, between first and second spaced-apart points on the patient's body so that current will flow along a path within the patient's body extending between said points, the arrangement of the current applying means being such that the current carrying path is confined substantially to the depth of the capillary bed, and means on the support body for enabling the voltage drop along at least part of the length of the current path within the patient's body be measured to provide an indication of the capillary blood flow rate.

6. A sensor device according to claim 5, further comprising means arranged to provide an indication if the blood flow rate assessed by the flow detector device falls below a predetermined level.

7. A sensor device according to claim 5 or 6, further comprising means arranged to prevent the effective use of the transcutaneous sensor if the blood flow rate assessed by the flow detector device falls below a predetermined level.

8. A sensor device according to claim 5, further comprising a visual display device arranged to

provide respective displays on the same time base of the instantaneous values of said property determined by the transcutaneous sensor, and of the blood flow rate assessed by the flow detector device.

9. A sensor device according to claim 5, 6, 7 or 8, wherein the transcutaneous sensor is a transcutaneous oxygen or CO_2 sensor for determining the partial pressure of oxygen or CO_2 in the bloodstream.

10. A sensor device for use in investigating substances in the bloodstream, substantially as hereinbefore described with reference to Figure 2 of the accompanying drawings.

New Claims or Amendments to Claims filed on 5/8/82
Superseded Claims All

New or Amended Claims:—

1. A sensor device to be held against a body surface of a patient for use in investigating substances in the bloodstream, comprising a support body, a transcutaneous sensor of the thermal stimulation type on the support body for determining non-invasively a property of a substance in a patient's bloodstream, which sensor comprises means for heating locally to a predetermined temperature the body surface of the patient in the area of action of the transcutaneous sensor, and a flow detector device for assessing non-invasively the blood flow rate in a region of the capillary bed positioned beneath the transcutaneous sensor, the flow detector device comprising means on the support body for applying alternating current, with the sensor device held against a body surface of the patient, between first and second spaced-apart points on the patient's body so that current will flow along a path within the patient's body extending between said points, the arrangement of the current applying means being such that the current carrying path is confined substantially to the depth of the capillary bed, and means on the support body for enabling the voltage drop along at least part of the length of the current path within the patient's body to be measured to provide an indication of the capillary blood flow rate.

2. A sensor device according to claim 1, further comprising means arranged to provide an indication if the blood flow rate assessed by the flow detector device falls below a predetermined level.

3. A sensor device according to claim 1 or 2, further comprising means arranged to prevent the effective use of the transcutaneous sensor if the blood flow rate assessed by the flow detector device falls below a predetermined level.

4. A sensor device according to claim 1, further comprising a visual display device arranged to provide respective displays on the same time base of the instantous values of said property, determined by the transcutaneous sensor, and of the blood flow rate assessed by the flow detector device.

5. A sensor device as claimed in any preceding claim, wherein the current applying means comprises first and second spaced-apart electrodes and the voltage drop measuring means comprises third and fourth electrodes both of which are arranged between the first and second electrodes and which are also spaced from one another.

6. A sensor device according to any preceding claim, wherein the transcutaneous sensor is a transcutaneous oxygen or CO_2 sensor for determining the partial pressure of oxygen or CO_2 in the bloodstream.

7. A sensor device for use in investigating substances in the bloodstream, substantially as hereinbefore described with reference to Figure 2 of the accompanying drawings.

8. A sensor as claimed in claim 1 and incorporating a flow detector substantially as hereinbefore described with reference to Figure 1 of the accompanying drawings.

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